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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,213	04/12/2001	Harukazu Fukami	001560-390	3646

7590 04/23/2004
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EXAMINER

HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,213

Applicant(s)

FUKAMI ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/23/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 14-17, 20-22, 26-29, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 32 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 17, 20, 22 and 33 is/are rejected.
- 7) ☒ Claim(s) 3, 14-16, 21 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/20/2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6, 14-17, 20-22, 26-29 and 32-33 are pending.

Response to Amendment

2. The amendment filed on 3/23/2004 in response to the previous Office Action (Paper No. 19) is acknowledged. Upon further review of the case, it is deemed necessary to raise new ground of rejection (obviousness rejection) over Fukami et al. US Pat. No. 5,814,631. Thus, the finality of the previous Office Action is withdrawn; the amendment is entered.

Objection

3. Claims 3, 14-17, 21 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-6, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukami et al. (US Pat. No. 5,814,631). The cited reference on column 52 (example 148) teaches the synthesis of 3-(4-aminobenzenesulfonyl)-7-

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chloro-2,4(1H,3H)-quinazolinedione. Said compound is almost the same as applicants when applicant's formula (1) has the following substituents:

X = chloro at 7 position; A = phenyl; R¹ = amino; R² = methyl; and R³ = hydrogen.

The only difference between applicant's compound and Fukami's species is that the substituent R². Applicant's compound formula (1) require that R² to be methyl, but Fukami's species has R² = hydrogen. The cited reference (Fukami et al.) on column 3 (line 22) teaches R¹ or R² = C1 to C4 lower alkyl. Specifically, it names methyl as an example of C1 to C4 lower alkyl on column 4 (line 11). Applicants are also directed to column 18 that discloses specific starting materials for preparing compounds of formula (I). Note that the starting material: 3,4-dimethylbenzensulfonylisocyanate (see column 18, lines 29-30) disclosed would produce a 3,4-dimethylsubstituted phenyl. Thus, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made to make change the hydrogen substituent to a methyl group. Applicants would be motivated to change the hydrogen substituent to a methyl group, because Fukami et al. already teaches a methyl substituent on the phenyl group (i.e. A = methylsubstituted phenyl) and Fukami also intends a starting material with dimethyl substituents on the phenyl group (i.e. A = 3,4-dimethylsubstituted phenyl).

In addition, compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. The homologue is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for

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preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ 425; *In re Druey*, 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. See also MPEP 2144.09, second paragraph.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of most of the diseases, does not reasonably provide enablement for the treatment of coronary diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There has been recited a method for the treatment of coronary diseases in general, but the specification is not enabled for such a scope.

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Coronary diseases embraces a vast array of problems, many of which are contradictory to others. It covers various types of arrhythmias; angina pectoris; the thrombotic symptoms of diabetes, atherosclerosis and hyperlipoproteinaemias; ischaemic heart disease including congestive heart failure and myocardial infarction; stroke, and peripheral vascular disorders, such as deep-vein thrombosis and thrombophlebitis percutaneous transluminal coronary angiography (PTCA); elevated blood levels of triglycerides, of total cholesterol or of LDL cholesterol; arteriosclerosis, peripheral vascular disease, cerebral vascular disease and pulmonary hypertension, migraine, cardiomyopathy, etc. Some other disorders of the heart include:

- **Heart murmur** - an audible vibration or humming heard through the stethoscope, caused by somewhat noisy blood flow within the heart. Faulty heart valves are a common cause, but usually the murmur does not indicate an abnormality.
- **Heart valve disorders** - for example, a faulty mitral valve allows blood to move backwards from the ventricle into the atrium. This condition is called mitral regurgitation.
- **Coronary heart disease** - fatty deposits or plaques build up inside one or more of the coronary arteries (atherosclerosis). This constant silting narrows the artery. Untreated, coronary heart disease can lead to angina or a heart attack.
- **Angina** - if the coronary arteries are narrowed, part of the heart muscle may not receive enough blood and oxygen. This causes the sensations of chest tightness and pain that are typical of angina.
- **Heart attack** - if a coronary artery is blocked, the heart is starved of oxygen and nutrients. Heart muscle cells (myocardial cells) are damaged, and may die without prompt treatment.
- **Congenital disorders** - the heart of a foetus may not develop properly. Problems include the blockage of blood flow inside the heart or blood vessels, abnormal flow of blood within the heart, or the heart itself may be underdeveloped.
- **Pericarditis** - inflammation or infection of the pericardium, which is the membrane surrounding the heart.

Not one compound --- let alone a genus of trillions of compounds, could possibly be effective against such disorders generally, especially in view of the fact that many of these cannot be treated pharmaceutically, e.g. valve disorders.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 17 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Regarding claim 17, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

b. In claims 6 and 32, the phrase "chymase inhibitor" should read as "chymase inhibitor composition", since it is a composition claim.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

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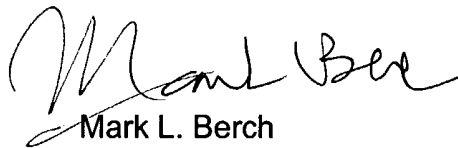
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
April 21, 2004